

REMARKS

Claims 1-39 are pending in this Application. Claims 9-11 and 16-39 have been withdrawn from consideration by the Examiner. In this Amendment and Response, Claims 9, 15, 17-20, 22-27, 29, 30, and 32-37 have been cancelled. Claims 1, 5, 10, 11, 28, and 31 have been amended. Claim 40 has been added.

Upon entry of this Amendment and Response, Claims 1-8, 10-14, 16, 21, 28, 31, and 38-40 will be pending in this Application with Claims 10, 11, 16, 21, 28, 31, 38, and 39 having been withdrawn from consideration by the Examiner.

Claim 1 has been amended, for example, to state that the method comprises administering a composition comprising a peptide that exhibits mammalian alpha-1-antitrypsin (AAT) or AAT-like activity and an antiviral nucleoside derivative. Claims 5, 10, and 11 have been amended to make them consistent with amended Claim 1.

Claim 28 has been amended by stating that the substance comprises one of the listed peptides or a combination thereof.

Claim Objections

Claims 9-11 and 16-39 are objected to allegedly because these claims were not written out on the Amendment and Reply filed on July 27, 2005. Examination of the file appears to indicate that these Claims were written out on the Amendment and Reply dated July 27, 2005. However, for the convenience of the Examiner, all the pending claims are provided with this Amendment and Response.

Rejection Under 35 USC §103(a)

Claims 1-8 and 12-14

Claims 1-8 and 12-14 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,532,215, issued to Lezday (the "Lezday Patent") and U.S. Patent 5,358,721, issued to Guittard et al. (the "Guittard et al. Patent"). The Office Action alleges that it would have been obvious to "combine the treatments of Lezday and Guittard et al. with the expectation of at least additive effect of the two treatments." See page 3 of the Office Action.

It is well established law that in order to establish a *prima facie* case of obviousness, Examiner must provide a sufficient evidence showing that the cited reference(s) provide some suggestion or motivation to modify or combine reference teachings. See MPEP §2145(X)(c).

Moreover, claims cannot be found obvious unless the prior art **teaches or suggests** making the claimed product. See *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) (The teaching or suggestion to make the claimed combination or modification and the reasonable expectation of success must **both be found** in the prior art), *In re Mills*, 16 USPQ2d 1430 (Fed. Cir., 1990) (The mere fact that references can be combined or modified does **not** render the resultant combination or modification obvious **unless** the prior art also **suggests the desirability** of the combination or modification.) There must be something in the prior art that would have motivated persons of ordinary skill to make the combination. *In re Stencel*, 4 U.S.P.Q.2d 1071, 1073 (Fed. Cir. 1987), *accord, Ex parte Marinaccio*, 10 U.S.P.Q.2d 1716 (Pat. Off. Bd. App. 1989) (combining references is improper absent some teaching, suggestion, or motivation for the combination in the prior art), *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990) (The mere fact that references can be combined or modified does **not** render the resultant combination or modification obvious **unless** the prior art also **suggests the desirability** of the combination or modification. Thus, although a prior art device “may be capable of being modified to run the way the apparatus is claimed, there **must be a suggestion or motivation in the reference** to do so”). In this respect, the following statement by the Patent Office Board of Appeals is noteworthy:

Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that “would lead” that individual “to combine the relevant teachings of the references.”... **Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant’s invention without also providing evidence of the motivating force that would impel one skilled in the art to do what the patent applicant has done.**

In re Levengood, 28 U.S.P.Q.2d 1300, 1302 (Pat. Off. Bd. App. 1993) (citations omitted; emphasis added).

As an initial matter, it is submitted that no motivation, suggestion or teaching is found in any of the cited references that would impel one skilled in the art to combine the teaching of the cited references in a manner suggested in the Office Action. Furthermore, no evidence is

provided in the Office Action that motivates, suggests or teaches one skilled in the art to combine the teachings of the cited references. The Office Action only provides a mere assertion that “One of ordinary skill in the art at the time of invention would have combined the treatments of Lezday and Guittard et al. with the expectation of at least additive effect of the two treatments.” See page 3 of the Office Action. This is paramount to “obvious to try” at best. It is well recognized that “obvious to try” is **not** the standard of 35 U.S.C. § 103(a). *In re Geiger*, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

More significantly, as discussed in detail below, it is submitted that rather than being impelled to combine the teachings of Lezday and Guittard et al., general knowledge of one skilled in the art would have lead to discouragement of combining the treatments disclosed in Lezday and Guittard et al.

According to the Office Action, the Lezday Patent discusses “treating...a herpes virus infection, eczema or related conditions with an AAT compound...”

The Guittard et al. Patent appears to be directed to providing “dispensing means for gastrointestinal delivery of antiviral drugs for obtaining antiviral hemodynamic effects that are free of fluid wash-out, and substantially independent of the variable environment of the gastrointestinal tract.” See, Col. 1, lines 48-53. In particular, it appears the Guittard et al. Patent discusses compositions and methods for administering an antiviral drug to the gastrointestinal tract of a human. See, for example, Claims 1 and 2.

Therefore, a combination of the Lezday Patent and the Guittard et al. Patent would appear to lead one skilled in the art to gastrointestinal delivery of antiviral drugs that includes AAT.

Claims of the present Application are directed to compositions and methods for using the composition, where the composition comprises a peptide. It is well known to one skilled in the art that peptides degrade significantly in gastrointestinal tract due to the presence of acid. See, for example, <http://www.maf.govt.nz/mafnet/rural-nz/research-and-development/pest-control/biological-management-of-possums/biological-management-of-possums-06.htm> (“Given that degradation of peptide and protein drugs is extensive within the gastrointestinal tract...”)

Therefore, contrary to the assertion in the Office Action, rather than being motivated to combine, it is submitted that one skilled in the art would be discouraged to combine teachings of the Lezday Patent with teachings of the Guittart et al. Patent. This is because, as the evidence above clearly shows, one skilled in the art knows that peptides are degraded extensively in the gastrointestinal tract, and the combination of the Lezday Patent and the Guittart et al. Patent would lead to one skilled in the art to gastrointestinal delivery of antiviral drugs that includes AAT (a protein).

In view of the above, it is respectfully submitted that the rejection of Claims 1-8 and 12-14 under 35 U.S.C. §103(a) over the Lezday Patent and the Guittart et al. Patent is improper and should be withdrawn.

Claims 1, 3, 4, and 15

Claims 1, 3, 4, and 15 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Lezday Patent in view of U.S. Patent No. 5,618,852, issued to Gyorkos et al. (the "Gyorkos et al. Patent") and the Guittard et al. Patent. As an initial matter, review of U.S. Patent No. 5,618,852 indicates that it is issued to Adkins and is entitled "Used Tire Process." Review of the prior Office Actions (May 7, 2003, paper No. 25) shows two Gyorkos et al. Patents were cited: U.S. Patent Nos. 5,618,792 and 5,891,852, which is a continuation-in-part of U.S. Patent No. 5,618,792. Examination of these two Gyorkos et al. Patents seems to indicate that most likely October 18, 2005, Office Action probably meant to refer to either U.S. Patent No. 5,618,792 or 5,891,852. Regardless of which Gyorkos et al. Patent the Office Action was meant to reference, the basis of relying on the Gyorkos et al. Patent appears to be that the Gyorkos et al. Patent discloses "a series of compounds including (Benzyloxycarbonyl)-L-valyl-L-N-[1-(2-[5-(3-methylbenzyl)-1,3,4-oxadiazolyl]carbonyl)-2-(S)-methylpropyl]-L-prolinamide...that are serine proteinase inhibitors...." See page 4 of the Office Action.

The compounds disclosed in the Gyorkos et al. Patents are directed "to certain substituted oxadiazole, thiadiazole and triazole peptoids...." See, for example, the Abstract of both of the Gyorkos et al. Patents. Therefore, the Gyorkos et al. Patent does not disclose peptides. Generally, peptoids are defined as "AMINO ACIDS composed of GLYCINE substituted at the nitrogen rather than the usual carbon position, resulting in the loss of HYDROGEN BONDING

donors. Polymers of these compounds are called PEPTOIDS.” See

<http://www.usc.hcn.com.au/subject.%60N-substituted%20Glycines%60/home.html>.

In contrast, Claims of the present Application have been amended to recite compositions comprising a peptide rendering this rejection moot.

Accordingly, it is respectfully requested that the rejection of Claims 1, 3, 4, and 15 under 35 U.S.C. §103(a) over the Lezday Patent in view of the Gyorkos et al. Patent and the Guittart et al. Patent be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully submitted that all claims now pending in this Application are in condition for allowance. Therefore, an early Office Action to that effect is earnestly solicited. If the Examiner believes a telephone conference would aid in the prosecution of this case in any way, please call the undersigned at (303) 955-8103.

Respectfully submitted,

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